DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ellipse Technologies, Incorporated
Ms. Rebecca Shelburne
Regulatory Affairs Specialist
13900 Alton Parkway, Suite 123
Irvine, California 92618-0000

October 7, 2014

Re: K141739
Trade/Device Name: Residual Limb Lengthening System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 9, 2014
Received: July 10, 2014

Dear Ms. Shelburne,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141739

Device Name
Residual Limb Lengthening System

Indications for Use *(Describe)*
The Ellipse Residual Limb Lengthening System is indicated for lengthening of the residual limb of the femur.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

13900 Alton Parkway, Suite 123
Irvine, California 92618 USA
Office: 949-837-3600
Fax: 949-837-3664
www.ellipse-tech.com

Ellipse Residual Limb Lengthening System
510(k) Summary – K141739
June 2014

1. Company: Ellipse Technologies, Incorporated
13900 Alton Parkway, Suite 123
Irvine, CA 92618

Contact: Rebecca Shelburne
Regulatory Affairs Specialist
Phone: (949) 837-3600 x227
Fax: (949) 837-3664

Date of Submission: June 26, 2014

2. Proprietary Trade Name: Ellipse Residual Limb Lengthening System

3. Classification Name: Intramedullary Fixation Rod (21 CFR 888.3020)

4. Product Code: HSB (Rod, Fixation, Intramedullary and Accessories)

5. Product Description: The Ellipse Residual Limb Lengthening (RLL) System is composed of the intramedullary RLL Nail (supplied sterile), locking screws, surgical instruments and an external remote controller (ERC). The RLL Nail has a 14 mm diameter with a telescoping distal end. The telescoping end has a 100 mm stroke length, making the RLL Nail capable of a maximum distracted length of 230 mm. The RLL Nail utilizes one distal and one proximal locking screw to secure the implant to the bone. The RLL Nail is supplied sterile by gamma radiation while the locking screws and instruments are supplied non-sterile and must be sterilized prior to use. The nail contains an enclosed rare earth magnet, telescoping lead screw/nut assembly, and planetary gearing. The Ellipse RLL System is a non-weight bearing device.

6. Indications: The Ellipse Residual Limb Lengthening System is indicated for lengthening of residual limb of the femur.

7. Substantial equivalence: Documentation that includes mechanical test results, design verification and detailed comparison to the predicate devices demonstrates that the Ellipse RLL System is substantially equivalent to the following 510(k) cleared device:

- Ellipse PRECICE® Intramedullary Limb Lengthening System (K141023)

Substantial equivalence is based on similar indications for use, technological characteristics, principles of operation, designs, and on *in vitro* testing performed.

ELLIPSE
13900 Alton Parkway, Suite 123
Irvine, California 92618 USA
Office: 949-837-3600
Fax: 949-837-3664
www.ellipse-tech.com

The Ellipse RLL System and the predicate device have the same intended use. Specifically, the RLL System and the predicate PRECICE System are both designed for limb lengthening. The RLL System is indicated for lengthening of the residual limb of the femur, specifically.

The Ellipse RLL Nail has similar technological characteristics and the same principles of operation as that of the predicate. Both the RLL Nail and the predicate PRECICE Nail are titanium intramedullary nails with a telescoping portion that can adjust the length of the limb using principles of distraction osteogenesis. Both devices are inserted into the intramedullary canal of the femur or tibia and secured with locking screws. Both devices are adjusted non-invasively by the Ellipse External Remote Controller (ERC).

Non-clinical testing on the RLL System included mechanical testing according to the methods outlined in the standard ASTM F1264-03, validation of the gamma radiation sterilization cycle in accordance with the VD_{max}^{25} methodology as given in ISO 11137-2 to verify that the gamma radiation sterilization process provides a sterility assurance level of 10^{-6}, and design verification and validation.

The following specific performance tests were completed on the RLL System in order to establish equivalence to the predicate device:

Test Description	Applicable Test Standard
Static Four Point Bend	ASTM F1264-03
Dynamic Four Point Bend	ASTM F1264-03
Static Torque to Failure	ASTM F1264-03
Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose	ANSI/AAMI/ISO 11137-2
Device functionality and verification	N/A

Tests that were performed on the predicate PRECICE System which are applicable to the RLL System include shelf life testing for the packaging after accelerated aging, O-ring seal performance testing and biocompatibility in accordance with ISO 10993-1 for the intended use of the device.

There are no changes to the design of the ERC being made as a result of this submission, therefore all testing that was performed on the predicate PRECICE System for the ERC are applicable to the RLL System.

Conclusions can be drawn from these tests that the RLL System is substantially equivalent to the predicate device.